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TITLE: Do Capacitively Coupled Electric Fields Accelerate Tibial Stress Fracture Healing

PRINCIPAL INVESTIGATOR: Andrew Hoffman, M.D.
Belinda Beck, Ph.D.
Gordon Matheson, M.D., Ph.D.
Gabrielle Bergman, M.D.

CONTRACTING ORGANIZATION: Stanford University
Stanford, California 94305-5401

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6. AUTHOR(S)
Andrew Hoffman, M.D.
Belinda Beck, Ph.D.
Gordon Matheson, M.D., Ph.D.
Gabrielle Bergman, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Stanford University
Stanford, California 94305-5401

E-Mail: b.beck@mailbox.gu.edu.au

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13. ABSTRACT ***(Maximum 200 Words)***

A convenience sample based on availability of tibial stress fracture cases at local Sports Medicine Clinics will be selected over 2-3 years until forty subjects (20 male, 20 female) have been treated. The study is designed to be able to determine if electric field stimulation accelerates the healing of tibial stress fracture and whether there are gender effects. Only posteromedial mid to distal third and proximal medical tibial condylar stress fractures will be investigated. Four imaging approaches will be used at diagnosis (radiographs, bone scan, MRI, and CT). All subjects will be identically treated in a double blind fashion using active or passive electric field stimulator devices that apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA, wearing the units for 15-20 hours per day, primarily at night, and other standardized rehabilitation treatments, until healed and not longer than 6 months. Subjects will be considered healed when hopping on the affected leg is no longer painful. Only MRI will be used for follow-up studies. A grading system will be developed for each of the diagnostic methods and compared to the ability of the MRI grading system to predict time to recovery.

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stress fracture, MRI, bone	5
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INTRODUCTION

This placebo-controlled study is designed to determine if electric field stimulation will accelerate the healing of tibial stress fractures. Additionally a stress fracture severity grading system is to be developed for four different diagnostic imaging techniques (plain films, nuclear medicine scans, MRI and CT). The purpose of the imaging study is to determine the most cost effective approach to tibial stress fracture diagnosis and the most effective technique to predict time to healing. Twenty male and 20 female subjects will be recruited in order to discriminate gender effects. All subjects are treated identically in a double blind fashion using active or inactive electric field stimulator devices that apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA. Subjects wear the units for 15-20 hrs/day until healed, with a maximum treatment time of 6 months. Subjects are considered healed when hopping on the affected limb is no longer painful.

BODY

Research accomplishments associated with tasks in approved Statement of Work

Preliminary activities to set up study in Australia:

Activity	Status
• Establish imaging protocols and costing with South Coast Radiology	Complete
• Liaise with Biolectron Inc. (now EBI) to coordinate ongoing supply of coded placebo and active OrthoPak units	Complete
• Submit Human Use documentation to Griffith University Human Subjects Ethics Committee	Complete
• Recruit and train research assistant	Complete
• Meet and discuss protocol with Sports Medicine Clinic physicians and other contact associations for recruiting	Complete
• Retrieve study devices, supplies, files and documentation from Stanford University	Complete

When the decision was made to subcontract the study to Griffith University from Stanford University in 2000, a Revised Statement of Work was submitted to the USAMRMC. The relevant 2001 and 2002 activities in the Revised Statement of Work included:

1. Interact with referring Sports Medicine Clinicians and Radiologists to maintain procedures and provide feedback
2. Consolidate recruiting base
3. Recruit ~ 21 subjects (over the 2001-2002 period)
4. Collect data, including: subject consenting, evaluation, consultation and data collection (Food Frequency and Activity History Questionnaires), radiology appointment making, OrthoPak training, monitoring
5. Prepare interim reports

Problems in accomplishing timeline tasks

The move of the Primary Investigator (Beck) to Griffith University, Australia prompted a Protocol re-review by USA HSRRB. This was only made apparent to the study PIs after the Protocol had been reviewed and approved by the Griffith University Human Ethics Committee and data collection had been initiated and completed on 5 subjects in Australia. Recruitment was then suspended while the USA HSRRB process ran its course. All USA HSRRB requirements have now been met and documentation revisions are currently under review by the Griffith University and Stanford University IRBs. See following excerpt of recent (October 1, 2002) email from Maryann F. Pranulis, RN, DNSc, Human Subjects Protection Scientist AMDEX:

"Dr. Beck,
Thank you for sending the revised consent document. It appears to meet all regulatory requirements. When you send the documentation of the GU and Stanford IRB approvals, send the copy of the consent document that they approve. This is the last step in the HSRRB approval of the amendments and the approval memo will be forwarded to the USAMRAA office where the official approval will be issued. You will receive a copy of that memo.
After you receive the official approval notification from USAMRAA, you will be able to resume recruiting and enrolling subjects."

As the process of re-review has been very protracted, our timeline goal of the collection of 21 more data sets in the time period 2001-2002 has not been possible. We are poised to re-initiate data collection immediately all IRB re-approvals are forthcoming.

KEY RESEARCH ACCOMPLISHMENTS

- Data collection on 14 subjects in total has been completed (9 at Stanford University and 5 at Griffith University)
- Subject data remains blinded from investigators until the end of the study
- Review of imaging and grade scale development will occur by three independent radiologists upon completion of full data set

REPORTABLE OUTCOMES

- No reportable outcomes to date (data is blinded)

CONCLUSIONS

- No reportable conclusions to date

REFERENCES

NA

APPENDICES

NA